Citation:

Yang G, Shu X-O, Jin F, Zhang X, Li H-L, Li Q, Gao Y-T, Zheng W. Longitudinal study of soy food intake and blood pressure among middle-aged and elderly Chinese women. *Am J Clin Nutr.* 2005: 81: 1,012-1,017.

PubMed ID: 15883423

Study Design:

Prospective cohort, longitudinal study

Class:

B - Click here for explanation of classification scheme.

Research Design and Implementation Rating:

NEUTRAL: See Research Design and Implementation Criteria Checklist below.

Research Purpose:

To examine the assoication between usual intake of soy foods and blood pressure among the participants in the Shanghai Women's Health Study, a large cohort study that was conducted in a population with a wide range of soy food intake.

Inclusion Criteria:

- Chinese women
- Aged 40 to70
- Residing in seven urban communities of Shanghai.

Exclusion Criteria:

Women were excluded from study if they had:

- History of hypertension (N=16,455)
- Diabetes (N=3,004)
- Coronary heart disease (N=5,068)
- Stroke (N=776)
- Antihypertensive medications (n=11,086)
- Postmenopausal hormones (N=1,409)
- Hysterectomy (N=3,701)
- Missing blood pressure data (N=46)
- Extreme total energy intake (less than 500 or greater than 3,500kcal per day) (N=9).

Description of Study Protocol:

- *Recruitment:* Shanghai Women's Health Study, initiated in March 1997, is a population-based prospective cohort study of Chinese women aged 40 to 70 years, residing in seven urban communities in Shanghai
- *Design:* Prospective cohort, longitudinal.

Statistical Analysis

- Multiple regression models were used to estimate mean differences in blood pressure associated with various intakes of soy foods
- Subjects were categorized into five groups according to daily soy protein intake with cut-offs being 2.5g (x-SD), 8.8g (mean), 15.1g (x+SD) and 25g per day (recommended by US Food and Drug Administration)
- Tests for interaction were performed by introducing a multiplicative interaction term into the main effect models.

Data Collection Summary:

Timing of Measurements

Usual intake of soy foods was assessed at baseline and blood pressure was measured two to threee years after the baseline survey.

Dependent Variables

- Blood pressure at baseline not measured, prevalence of hypertension based on self-report
- Blood pressure measured at follow-up using conventional mercury sphygmomanometer and standard protocol.

Independent Variables

- Soy intake based on validated food frequency questionnaire
- Soy and isoflavone intake estimated using Chinese Food Composition Table.

Control Variables

- Age
- BMI
- Education
- Household income
- Alcohol consumption
- Cigarette smoking
- Regular physical activity
- Other dietary factors.

Description of Actual Data Sample:

Initial N

- 81,170 eligible women from Shanghai registry
- 2,407 refused to participate
- 2,073 were not available during the study recruitment period and 1,469 were not enrolled for

miscellaneous reasons such as mental disorder
- Remaining 75,221 women were recruited
- Final cohort consisted of 74,943 women.

Attrition (Final N)

- 45,694 women remained for analysis
- Many excluded after application of exclusion criteria.

Age

Mean, 49.9±8.5 years.

Ethnicity

All Chinese.

Location

Shanghai, China.

Summary of Results:

Soy Protein Intake (g/day)	SBP, fully adjusted	DBP, fully adjusted
<2.5 (N=4,007)	0.0 (reference)	0.0 (reference)
2.5-8.7 (N=23,273)	-0.2 (-0.7, 0.3)	-0.2 (-0.6, 0.1)
8.8-15.0 (N=12,859)	-0.5 (-1.0, 0.1)	-0.4 (-0.7, -0.1)
15.1-24.9 (N=4,560)	-0.3 (-1.0, 0.4)	-0.4 (-0.8, 0.0)
>25 (N=995)	-1.9 (-3.0, -0.8)	-0.9 (-1.6, -0.2)
P for trend	0.01	0.009

Other Findings

- Soy protein intake was inversely associated with both systolic blood pressure (P for trend = 0.01) and diastolic blood pressure (P for trend = 0.009) after adjustment for age, BMI and lifestyle and other dietary factors
- The adjusted mean systolic BP was 1.9mm Hg lower (95% CI: -3.0, -0.8mm Hg) and the diastolic BP was 0.9mm Hg lower (95% CI: -1.6, -0.2mm Hg) in women who consumed over 25g soy protein per day than in women consuming less than 2.5g per day
- The inverse associations became stronger with increasing age (P for interaction <0.05 for both BPs)
- Among women over 60 years old, the corresponding differences were -4.9mm Hg (95% CI: -8.0, -1.9mm Hg) for systolic BP and -2.2mm Hg (95% CI: -3.8, -0.6mm Hg) for diastolic BP.

Author Conclusion:

- In summary, we found in this large longitudinal study that usual intake of soy foods was

significantly and inversely associated with both systolic and diastolic blood pressures, particularly among late postmenopausal women
- Although the magnitude of reduction in blood pressure associated with daily consumption of over 25g soy protein in the whole cohort of healthy women may not have significant clinical relevance, the public health implications may be important, given that a small reduction in populationwide blood pressure can lead to a substantial decrease in cardiovascular risk in the society
- These data lend further support to the recommendation to increase consumption of soy foods to promote cardiovascular health.

Reviewer Comments:

- *Large sample size and high response rates*
- *Adjusted for many confounding variables*
- *Baseline blood pressure not measured and presence of HTN based on self-report*
- *Authors note limitations of only measuring blood pressure once and that subjects may have changed their diets since baseline.*

Research Design and Implementation Criteria Checklist: Primary Research

Relevance Questions		
1.	Would implementing the studied intervention or procedure (if found successful) result in improved outcomes for the patients/clients/population group? (Not Applicable for some epidemiological studies)	N/A
2.	Did the authors study an outcome (dependent variable) or topic that the patients/clients/population group would care about?	Yes
3.	Is the focus of the intervention or procedure (independent variable) or topic of study a common issue of concern to nutrition or dietetics practice?	Yes
4.	Is the intervention or procedure feasible? (NA for some epidemiological studies)	Yes
Validity Questions		
1.	**Was the research question clearly stated?**	Yes
1.1.	Was (were) the specific intervention(s) or procedure(s) [independent variable(s)] identified?	Yes
1.2.	Was (were) the outcome(s) [dependent variable(s)] clearly indicated?	Yes
1.3.	Were the target population and setting specified?	Yes
2.	**Was the selection of study subjects/patients free from bias?**	Yes

2.1.	Were inclusion/exclusion criteria specified (e.g., risk, point in disease progression, diagnostic or prognosis criteria), and with sufficient detail and without omitting criteria critical to the study?	Yes
2.2.	Were criteria applied equally to all study groups?	Yes
2.3.	Were health, demographics, and other characteristics of subjects described?	Yes
2.4.	Were the subjects/patients a representative sample of the relevant population?	Yes
3.	**Were study groups comparable?**	N/A
3.1.	Was the method of assigning subjects/patients to groups described and unbiased? (Method of randomization identified if RCT)	N/A
3.2.	Were distribution of disease status, prognostic factors, and other factors (e.g., demographics) similar across study groups at baseline?	N/A
3.3.	Were concurrent controls used? (Concurrent preferred over historical controls.)	N/A
3.4.	If cohort study or cross-sectional study, were groups comparable on important confounding factors and/or were preexisting differences accounted for by using appropriate adjustments in statistical analysis?	N/A
3.5.	If case control or cross-sectional study, were potential confounding factors comparable for cases and controls? (If case series or trial with subjects serving as own control, this criterion is not applicable. Criterion may not be applicable in some cross-sectional studies.)	N/A
3.6.	If diagnostic test, was there an independent blind comparison with an appropriate reference standard (e.g., "gold standard")?	N/A
4.	**Was method of handling withdrawals described?**	Yes
4.1.	Were follow-up methods described and the same for all groups?	Yes
4.2.	Was the number, characteristics of withdrawals (i.e., dropouts, lost to follow up, attrition rate) and/or response rate (cross-sectional studies) described for each group? (Follow up goal for a strong study is 80%.)	Yes
4.3.	Were all enrolled subjects/patients (in the original sample) accounted for?	Yes
4.4.	Were reasons for withdrawals similar across groups?	Yes
4.5.	If diagnostic test, was decision to perform reference test not dependent on results of test under study?	N/A
5.	**Was blinding used to prevent introduction of bias?**	No

5.1.	In intervention study, were subjects, clinicians/practitioners, and investigators blinded to treatment group, as appropriate?	N/A
5.2.	Were data collectors blinded for outcomes assessment? (If outcome is measured using an objective test, such as a lab value, this criterion is assumed to be met.)	No
5.3.	In cohort study or cross-sectional study, were measurements of outcomes and risk factors blinded?	No
5.4.	In case control study, was case definition explicit and case ascertainment not influenced by exposure status?	N/A
5.5.	In diagnostic study, were test results blinded to patient history and other test results?	N/A
6.	**Were intervention/therapeutic regimens/exposure factor or procedure and any comparison(s) described in detail? Were interveningfactors described?**	Yes
6.1.	In RCT or other intervention trial, were protocols described for all regimens studied?	N/A
6.2.	In observational study, were interventions, study settings, and clinicians/provider described?	Yes
6.3.	Was the intensity and duration of the intervention or exposure factor sufficient to produce a meaningful effect?	Yes
6.4.	Was the amount of exposure and, if relevant, subject/patient compliance measured?	Yes
6.5.	Were co-interventions (e.g., ancillary treatments, other therapies) described?	N/A
6.6.	Were extra or unplanned treatments described?	N/A
6.7.	Was the information for 6.4, 6.5, and 6.6 assessed the same way for all groups?	Yes
6.8.	In diagnostic study, were details of test administration and replication sufficient?	N/A
7.	**Were outcomes clearly defined and the measurements valid and reliable?**	Yes
7.1.	Were primary and secondary endpoints described and relevant to the question?	Yes
7.2.	Were nutrition measures appropriate to question and outcomes of concern?	Yes
7.3.	Was the period of follow-up long enough for important outcome(s) to occur?	Yes
7.4.	Were the observations and measurements based on standard, valid, and reliable data collection instruments/tests/procedures?	Yes
7.5.	Was the measurement of effect at an appropriate level of precision?	Yes
7.6.	Were other factors accounted for (measured) that could affect outcomes?	Yes

	7.7.	Were the measurements conducted consistently across groups?	N/A
8.	**Was the statistical analysis appropriate for the study design and type of outcome indicators?**		Yes
	8.1.	Were statistical analyses adequately described and the results reported appropriately?	Yes
	8.2.	Were correct statistical tests used and assumptions of test not violated?	Yes
	8.3.	Were statistics reported with levels of significance and/or confidence intervals?	Yes
	8.4.	Was "intent to treat" analysis of outcomes done (and as appropriate, was there an analysis of outcomes for those maximally exposed or a dose-response analysis)?	N/A
	8.5.	Were adequate adjustments made for effects of confounding factors that might have affected the outcomes (e.g., multivariate analyses)?	Yes
	8.6.	Was clinical significance as well as statistical significance reported?	Yes
	8.7.	If negative findings, was a power calculation reported to address type 2 error?	No
9.	**Are conclusions supported by results with biases and limitations taken into consideration?**		Yes
	9.1.	Is there a discussion of findings?	Yes
	9.2.	Are biases and study limitations identified and discussed?	Yes
10.	**Is bias due to study's funding or sponsorship unlikely?**		Yes
	10.1.	Were sources of funding and investigators' affiliations described?	Yes
	10.2.	Was the study free from apparent conflict of interest?	Yes